

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DISVISION AT COOKEVILLE

ANDREW SCOTT RODRIGUEZ,

Plaintiff,

vs.

STRYKER CORPORATION, a Michigan
Corporation; STRYKER SALES
CORPORATION, a Michigan corporation,

Defendants.

C.A. No. 2:08-cv-124

JUDGE ALETA A. TRAUGER
MAGISTRATE BRYANT

JURY DEMAND

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO EXCLUDE YADIN DAVID, ED.D.**

Pursuant to Rules 401, 403, and 702 of the Federal Rules of Civil Procedure, Defendants Stryker Corporation and Stryker Sales Corporation (collectively “Stryker”) file this Motion to Exclude Yadin David, Ed.D. as follows:

SUMMARY OF ARGUMENT

Dr. David’s proposed testimony is irrelevant and, in fact, flies in the face of the Supreme Court’s decision in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001). As a preliminary matter, his testimony largely consists of legal opinions, some of which get the law wrong. The Sixth Circuit simply prohibits that sort of testimony.

Moreover, Dr. David’s testimony focuses specifically on whether Stryker violated federal statutes and regulations regulating prescription devices. In *Buckman*, the Supreme Court made it clear that the federal government had *exclusive* jurisdiction to enforce those statutes and regulations. Allowing Dr. David to rely on this testimony will effectively allow him to serve as a private attorney general in violation of *Buckman*. Instead, the trial of this case should focus on

Stryker's liability under Tennessee law. Allowing testimony of federal regulations would only serve to confuse the jury and prejudice Stryker.

This Court should also reject Dr. David's testimony for a host of more traditional reasons. First, Dr. David lacks expertise regarding his subject matter—regardless of whether the Court considers the product at issue (pain pumps), the subject of his criticisms (warnings for prescription devices), or the agency that regulates prescription drugs (the FDA). Dr. David also did not conduct the basic foundational work necessary for a legitimate opinion about the adequacy of the warnings. Most notably, Dr. David did not even bother to conduct a literature search to determine the magnitude of the risk. This Court should not allow him to testify about the adequacy of the warnings when he has no basis to estimate the seriousness of the risk. Nor has Dr. David confirmed that Stryker had knowledge of the risk at the relevant time.

DAUBERT STANDARDS

Before an expert can express a causation opinion in a federal case, the following factors must be satisfied: (1) the expert must seek to testify regarding “scientific, technical, or other specialized knowledge”; (2) the expert must be qualified to express an opinion on the topic; (3) the expert’s opinion must be relevant; (4) the expert’s opinion must be reliable; and (5) the proffered testimony must be “otherwise admissible.” *See* FED. R. EVID. 702; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590-95 (1993).

The U.S. Supreme Court directed trial courts to serve as “gatekeepers” to ensure that, consistent with Rule 702, “any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert*, 509 U.S. at 589 (emphasis added). Although *Daubert* focused specifically on “scientific” testimony, the Supreme Court has made it clear that all expert testimony must meet the rigors articulated in that case. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

The relevance aspect of the *Daubert* test is just as much a part of Rule 702 as the reliability portion. *See Daubert*, 509 U.S. at 589 (“Rule 702 further requires that the evidence or testimony ‘assist the trier of fact to understand the evidence or to determine a fact in issue.’ This condition goes primarily to relevance. ‘Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.’”) (citations omitted).

Following *Daubert*, the Sixth Circuit has made it clear that in performing the inquiry into admissibility of an expert’s testimony, a court should assess the relevancy requirement by determining whether there is a “fit” between the testimony and the issues to be resolved in the case. *See United States v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993). As to reliability or the foundational requirements of an expert’s proffered testimony, the focus should be on the methodology and principles underlying the testimony. *Id.* at 556; *Greenwell v. Boatwright*, 184 F.3d 492, 495-96 (6th Cir. 1999).

ARGUMENT

I. Dr. David’s Testimony about Alleged FDA Violations is Irrelevant and Prejudicial.

Dr. David’s testimony about alleged FDA violations is absolutely irrelevant under Rule 702 as well as Rules 401 and 403. First, he tries to usurp the role of the courts—by providing legal conclusions about whether the pain pump at issue was “misbranded” or “adulterated” under the Food Drug and Cosmetic Act (“FDCA”). Indeed, Dr. David gets the law *wrong*. There is no reason to subject the jury to such prejudicial testimony.

Perhaps more importantly, Dr. David also tries to usurp the role of the FDA. Under the Supreme Court’s 2001 decision in *Buckman*, the FDA has exclusive jurisdiction to determine whether medical devices are “misbranded” or “adulterated.” *Buckman* represents a sea-change in the law. Under *Buckman*, Plaintiff cannot rely on allegations of misbranding to state a claim. This Court should enforce those limits at trial and strike this testimony.

A. Dr. David Merely Seeks to Interpret the Federal Drug and Cosmetic Act and the FDA’s Regulations under the Act.

This Court should exclude virtually all of Dr. David’s testimony on the basis that it constitutes an impermissible and irrelevant legal opinion. The Sixth Circuit prohibits legal opinion testimony for the obvious reason that the Court is the exclusive source of the law for the jury. *See Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985) (“This ‘invade[s] the province of the court to determine the applicable law and to instruct the jury as to that law.’”)(citations omitted). This prohibition on legal opinion testimony applies to experts. *See Woods v. Lecureux*, 110 F.3d 1215, 1220 (6th Cir. 1997) (“It is, therefore, apparent that testimony offering nothing more than a legal conclusion—*i.e.*, testimony that does little more than tell the jury what result to reach—is properly excludable under the Rules.”).

In fact, the Sixth Circuit has endorsed a practical test for determining whether to exclude legal opinions that is designed to exclude all blatant legal conclusions—which are flatly inappropriate. *See Torres*, 758 F.2d at 151 (“The best resolution of this type of problem is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular. If they do, exclusion is appropriate.”) (citing cases).

Here, Dr. David was hired precisely to give an opinion about “complying with legal regulatory issues.” *See* Deposition of Yadin David, Ed.D. (dated Oct. 5, 2010), attached as **Exhibit A** (hereinafter “David Depo.”) at 27. Indeed, essentially all of his opinions involve legal conclusions about alleged FDA violations—particularly allegations of “misbranding” under federal law:

- **Opinion #1:** Regarding Stryker’s alleged manufacture and marketing of an “unsafe device,” Dr. David opines “there is non-compliance with the law, specifically the Act 301, 501 and 515, Section 515, and irregardless of patients’

safety by not correcting those issues initially when they introduced the device and later on where more reports came out about it.” *Id.* at 101 (emphasis added).

- **Opinion #2:** Regarding Stryker’s allegedly misleading warnings, Dr. David opines “Stryker’s device labeling was misleading which in effect misbranded the device” *Id.* at 105 (emphasis added).
- **Opinion #3:** Regarding Stryker’s allegedly ambiguous warnings, Dr. David opines that “Stryker had a duty under the Act and related regulations to ensure the safety of its infusion pain pumps [Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 301].” *See Report of Dr. Yadin David in the case of Rodriguez v. Stryker Corp., et al.*, attached as **Exhibit B** (hereinafter “David Report”) at 8.
- **Opinion #4:** Regarding Stryker’s reporting requirements to the FDA, Dr. David opines that Stryker violated federal regulations and the FDCA. *See David Depo.* at 108-09.

When pressed about the above “legal opinions,” Dr. David freely admitted that he was merely “reading the law”:

Q. So you are in effect, as an expert, saying that you are interpreting the FDA regulations and you are giving an opinion that under those regulations, this was in effect misbranding?

A. No, it’s not my interpretation. Sorry. These --

Q. Well, it’s your opinion, then?

A. The opinion is based on legal documents. The legal documents are specifying the penalty for misbranding and outlines what misbranding is. It’s written. It’s not my interpretation. It’s written in the law.

Q. All right. So you are reading the law, the FDA regulations, right?

A. Yes.

David Depo. at 106.

B. Dr. David Wrongly Interprets the Law.

Even if Dr. David could testify as to the law in this Circuit, he gets the law wrong.

See Torres, 758 F.2d at 150 (“The problem with testimony containing a legal conclusion is in

conveying the witness' unexpressed, and perhaps erroneous, legal standards to the jury.”). The most egregious example is where Dr. David attacks Stryker for failing to stop “off label” use of the pain pumps:

Even though Stryker was refused approval for applying the pumps in the joint space and knew that surgeons were doing so, Stryker did not communicate to the community of orthopedic surgeons the need to correct this misuse.

David Report at 10 (emphasis added).

Stryker, however, has absolutely no duty to tell doctors how to practice medicine. In fact, the Supreme Court has recognized that “off label” use is not a “misuse”—but instead it is entirely appropriate. *Buckman*, 531 U.S. at 350 (“Similarly, ‘off-label’ usage of medical devices ... is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.”); *see also King v. Danek Medical, Inc.*, 37 S.W.3d 429, 458 (Tenn. Ct. App. 2000) (explaining that off label use of medical devices is “not prohibited” and is “recognized by the FDA”).

It is hard to overstate the importance of this mistake. The heart of Dr. David’s opinion is that Stryker should have told doctors that the FDA had not approved the pain pump for use in the intra-articular space in the shoulder. *See generally* David Report at 3-8; *see also id.* at 6 (“Stryker did not communicate to him [Utah physician, Dr. Lonnie Paulos] any information that would have made him aware that the safety of the PainPumps [sic] was not studied or validated when applied in the synovial space”).

Aside from Dr. David’s criticism of “off label” use, Dr. David also attacks Stryker for alleged “off label” promotion. Of course, Dr. David is correct that any alleged “off label” promotion would violate federal law. Dr. David, however, goes further and implies that this violates the standard of care. *See* David Report at 6 (“Upon learning that the FDA refused to

approve the synovial space application, a prudent reasonable corporation must refrain from marketing their device for such application, unless it can bring data that support safer application.”).

Under Tennessee law, however, FDA regulations do not establish the standard of care. Instead, the “administrative requirement that a given device be approved by the FDA before being marketed” is merely “a tool to facilitate administration of the underlying regulatory scheme.” *King*, 37 S.W.3d at 457 (quoting *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999)). In other words, that FDA requirement “lacks any independent substantive content, it does not impose a standard of care” *Id.* (quoting *Talley*). There is no basis for allowing the jury to hear irrelevant “expert” testimony that wrongly excoriates Stryker for allegedly breaking a regulation that does not impose a standard of care under Tennessee law. *See* FED. R. EVID. 403.

It is also worth noting that Dr. David also wrongly invokes the labeling standards for providing “[a]dequate directions for use” for *laymen*. *See* David Report at 9 (citing 21 C.F.R. § 801.5). Of course, that standard is irrelevant to the use of a surgical device by a physician. But it also appears to be wrong on the law, as Dr. David does not account for the exceptions to that regulation for *prescription* devices under 21 C.F.R. § 801.109.

C. Dr. David Tries to Serve as a Private Attorney General.

Perhaps more importantly, Dr. David’s testimony is also irrelevant because it consists of explanations about why Stryker’s pain pump is allegedly “misbranded” and “adulterated” under the FDCA. In short, the use of this testimony in a private lawsuit would ignore the Supreme Court’s conclusion that there is no private enforcement of the FDCA. *See Buckman*, 531 U.S. at 349 n.4 (“The FDCA leaves no doubt that it is the Federal Government

rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions") (interpreting 21 U.S.C. § 337(a)).

Indeed, the Tennessee courts have already ruled that FDA regulatory evidence is irrelevant to Tennessee product liability causes of action:

In the instant cases, the plaintiffs are required to prove that the fixation devices were defective or unreasonably dangerous at the time they left the manufacturer's control. It appears from our review of the record that the evidence excluded by the trial court and offered in proof does not tend to prove the determinative issues in the case nor lead to evidence that would prove such issues. The FDA's approval or nonapproval of the devices without more does not tend to prove that the devices were defective or unreasonably dangerous.

Bish v. Smith & Nephew Richards, Inc., 2000 WL 1294324, *5 (Tenn. Ct. App. Aug. 23, 2000) (emphasis added) (copy attached as **Exhibit C**); *see also King*, 37 S.W.3d at 457 (holding that testimony about FDA regulations is irrelevant as to standard of care).

Indeed, the unanimous *Bish* Court unequivocally held that the resulting prejudice and confusion from testimony about alleged FDA violations would easily outweigh the probative value of the testimony:

Moreover, a review of the testimony of the three witnesses offered by plaintiff Burton aptly illustrates the reason for Tenn. R. Evid. 403. The introduction of the proof concerning the FDA activity in regulation would result in a confusion of the issues, could mislead the jury, and without question would result in undue delay and a waste of time. Under the state of this record, if there is any probative value to the testimony, it is substantially outweighed by the dangers outlined in Rule 403.

Bish, 2000 WL 1294324, at *5.

At the federal level, court after court has recognized that private parties cannot enforce the FDCA—particularly its prohibitions on “misbranded” and “adulterated” devices. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, -- F.3d --, 2010 WL 4026802, *2

(8th Cir. Oct. 15, 2010) (only the United States may enforce “FDA requirements”); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (citing cases); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (“[P]laintiff … cannot escape preemption by reference to provisions of the FDCA that govern the sale of adulterated and misbranded devices because there is no private right of action under the FDCA.”) (emphasis added); *Lewkut v. Stryker Corp.*, -- F. Supp. 2d --, 2010 WL 1544275, *8 (S.D. Tex. April 16, 2010) (“[T]he statutory language of the FDCA, as well as case law, makes clear that the provisions of the FDCA, including that which establishes and defines the prohibition on ‘adulterated devices’, are to be enforced through the United States government only.”) (emphasis added).

Ultimately, Plaintiff is attempting to use Dr. David’s testimony to enforce laws that he has no business enforcing. *See id.* (“[C]ourts have held that that private enforcement of FDCA regulations via state common law would interfere with this regulatory scheme and is therefore prohibited.”) (citing *Buckman*).

Moreover, Dr. David admits that the FDA has never engaged any enforcement procedures regarding Stryker’s pain pumps for potentially being misbranded or adulterated. David Depo. at 80-81. This also demonstrates that Dr. David’s opinions are unreliable. He purports to establish major violations of federal regulatory law while the authorities charged with *exclusive* enforcement of that law think nothing of it. Out of deference to the FDA, this Court should strike this testimony. *See Mass v. McDonald’s Corp.*, 2004 WL 2624255, *3 (N.D. Tex. Nov 12, 2004) (“The FDCA … vests enforcement authority exclusively in the federal government.”) (copy attached as **Exhibit D**).

D. Dr. David's Criticisms of the Label Are Irrelevant Because the Treating Physician Did Not Read the Label.

In contrast to Dr. David's testimony about federal law, the relevant issue should be the adequacy of Stryker's warning under *Tennessee* products liability law. *See Bish*, 2000 WL 1294324, at *5. But, ironically, any testimony about the adequacy of the warning is irrelevant in *this* case—because there is no evidence that the treating doctor, Dr. John Kuhn, read the relevant warnings. *See* Deposition of Dr. John E. Kuhn, attached as **Exhibit E**, at 55 (“Q. First, as you sit here today, do you recall reviewing Stryker's instructions for use? A. I don't recall it.”).

Indeed, Dr. Kuhn first started using pain pumps during his tenure at the University of Michigan from 1994 to 2004. *Id.* at 13. He established his protocol for using pain pumps while at Michigan, and did not change it thereafter, even after his arrival at Vanderbilt in 2004. *Id.* at 13-14. Moreover, Dr. Kuhn's initial decision to use pain pumps and his determination of their indications and contraindications was driven, not by any information from Stryker, but rather by the medical literature. *Id.* at 62-63 & 21; *see also id.* at 63 (“Q. Do you remember at least speaking with sales people from Stryker at some point during this learning curve? A. I don't.”).

Of course, when Dr. Kuhn first starts to use a new product, he generally looks at the literature from the manufacturer. *Id.* at 63; *see also id.* at 57. But in this case, Dr. Kuhn's possible review of the warnings from the 1990s would be irrelevant. The only relevant issue is whether Dr. Kuhn would have reviewed the updated warnings that Plaintiff proposes in November 2004. The answer to that is no. *See id.* at 55 (Dr. Kuhn does not recall reviewing the relevant “instructions for use”). In fact, Dr. Kuhn does not normally review the “instructions for use” unless he is unfamiliar with the device. *See id.* at 55. Of course, Dr. Kuhn was familiar

with Stryker's pain pumps by November 2004. *See id.* at 13-15 (indicating that Dr. Kuhn had performed 350 shoulder surgeries a year back when he was in Michigan).

In summary, there is no evidence that Dr. Kuhn would have ever read an updated warning from Stryker—while there is affirmative evidence denying that Dr. Kuhn remembers reading the relevant warnings. Additionally, it is also worth noting that Dr. Kuhn did not rely on any conversations with Stryker's sales representatives for his use of pain pumps. *Id.* at 17-18 & 63. He also cannot recall how he learned what medicines to use with the pain pumps or how he learned about where to place the catheter for the pain pump. *See id.* at 16-17.

In light of this evidence that Dr. Kuhn did not even read Stryker's current warnings, Dr. David's opinions about whether those warnings violated FDA regulations are irrelevant for this reason as well. This conclusion is so obvious that Dr. David admitted to it:

Q. ... [G]iven what Dr. Kuhn said about not reviewing the label, can you state that -- with any degree of certainty that if the changes you think should have been made had been made, that Mr. Rodriguez would not have suffered the same ultimate event?

A. I think that we discussed earlier today that Dr. Kuhn is an experienced user of pain pumps, and that after looking at the new device once and listening to the sales rep maybe once, that not necessarily he will look at the instructions for use again.

So my opinion will be that there are other methods that are very applicable to deliver the message of "Dear Doctor or Orthopedic Surgeons, there are changes to the instructions for use, we would like you to know them."

Q. Okay. But given what he said, a simple change to the instructions for use may not have had any effect at all?

A. In this case it may or may not, correct.

See David Depo. at 129-30. Similarly, as a matter of Tennessee law, there is no "warning causation" when the treating doctor did not rely on the warnings:

King and Little, as did the plaintiff in Harden, have failed to establish that the defendants' alleged failure to warn was the proximate cause of their injuries. Both of the plaintiffs' implanting physicians were well experienced in the use of internal fixation devices utilizing pedicle screws. Both testified that they relied upon their own knowledge and judgment in deciding to implant the devices into the plaintiffs. The plaintiffs have not shown that these decisions were influenced by any representation which the defendants made or failed to make. Thus, the plaintiffs' claims in this regard fail because they have failed to establish that, had additional warnings been given, the plaintiffs would not have sustained their injuries.

King, 37 S.W.3d at 453 (emphasis added & citations omitted); *see also Cansler v. Grove Mfg. Co.*, 826 F.2d 1507, 1510-11 (6th Cir. 1987) (overturning product liability judgment because plaintiff failed to prove, *inter alia*, that a defect in the warning caused the injury) (applying Tennessee law).

Significantly, this Court has recognized that “[t]he key inquiry” in a warnings case “is whether, ‘had additional warnings been given, the plaintiffs would not have sustained their injuries.’” *Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010) (Trauger, J.) (quoting *King*). Here, without any evidence that Dr. Kuhn would have even read any updated warnings, the answer is no.

E. Dr. David's Opinion Largely Consists of Reciting Other Alleged Evidence—Often Incorrectly.

Dr. David's proffered testimony is also irrelevant because it consists largely of simply reciting factual evidence. *See, e.g.*, David Depo. at 34 (using the euphemism “[r]eflecting on documented facts”). In short, the jury can read the documents and listen to the testimony itself—it does not need Dr. David to do that for them. *See U.S. v. Pollard*, 128 F. Supp. 2d 1104, 1124 (E.D. Tenn. 2001) (“the court must determine whether expert testimony will assist the jury in resolving a question of fact or whether such expert testimony will simply make the job of the

jury more difficult"). Therefore, the proposed testimony is not helpful to the jury under Rule 702 and *Daubert*.

For example, Dr. David's expert report extensively attacks Stryker for alleged off label promotion. But to reach the "expert opinion" that Stryker is promoting off label, Dr. David almost exclusively relies on one Utah doctor's recollection of off-label promotion. *See* David Report at 4-5 (quoting the testimony of Dr. Lonnie Paulos). Whether the jury should believe Dr. Paulos' recollection is a classic fact issue that the jury can judge for itself. Nor is there is no reason for this Court to allow an expert to extrapolate about the significance of one Utah doctor's memory or perceptions to the rest of the country or to Tennessee in particular. In fact, these allegations are vigorously disputed. *See* David Depo. at 81 (admitting that the FDA has never accused Stryker of off label promotion).

Indeed, as just discussed, Dr. David's testimony about off label promotion is actually irrelevant because the treating doctor in this case did not rely on *any* conversations with Stryker's sales representatives for his use of pain pumps. *See* Deposition of Dr. John E. Kuhn at 17-18 & 63.

In addition, Dr. David does not faithfully interpret the facts that he is reciting. For example, Dr. David concludes that Stryker's promotional material created confusion among the doctors about the FDA's approval of pain pumps. *See* David Depo. at 34-39. But Dr. David did not discuss the alleged confusion with any doctor. *Id.* at 36. Nor was Dr. David able to point to any testimony where a doctor admitted to any alleged confusion. *See id.* at 34-39; *see id.* at 38 ("I think that perhaps the word 'confusion' is not there"). Instead, Dr. David merely imposed his subjective beliefs onto the doctor's testimony to reach his conclusion. *See id.* at 39 ("I believe that I am reading sentences describing a state of confusion.").

Perhaps not surprisingly, Dr. David claimed that his opinions about the doctors' alleged confusion is self-evident—and thus does not constitute expert testimony:

Q. Okay. So for example, a judge or a jury could read those same statements and you feel they would come to the same conclusion that you have?

A. I do.

Q. It doesn't really require an expert to get to that conclusion, is that what you are saying?

A. Yeah. You just need to know the spaces, yes.

Id. at 39.

In summary, many of Dr. David's "expert opinions" are merely his lay opinions resolving the factual issues for the jury. At best, this is just Dr. David's interpretations of someone's testimony—which the jury could do for itself. At worst, it is Dr. David's attempt to impose his own meaning onto the deposition testimony.

II. Dr. David Is Not Qualified to Give the Opinions He Purports to Provide.

Even if Dr. David's opinions about Stryker's warnings were relevant, he is not qualified to give them. Under Rule 702, a proposed expert must have *relevant* "scientific, technical, or other specialized knowledge" that is helpful to the jury. *See FED. R. CIV. P. 702; Pride v. Bic Corp.*, 54 F. Supp. 2d 757, 761 (E.D. Tenn. 1998) *aff'd* 218 F.3d 566 (6th Cir. 2000) ("None of the plaintiff's experts qualify as an expert by 'knowledge, skill, experience, training, or education' to offer an expert opinion regarding a manufacturing defect in the lighter.").

Here, Dr. David's *relevant* qualifications are entirely missing:

- He has no experience with pain pumps.
- He is not a warnings expert.
- He is not an FDA expert.

Yet Plaintiff offers Dr. David's testimony precisely about these three issues—*i.e.*, whether the warnings on Stryker's pain pumps were adequate under FDA standards. On its face, Rule 702 prohibits this testimony. *See* FED. R. EVID. 702.

A. Dr. David Is Not a Pain Pump Expert.

The most glaring omission in Dr. David's qualifications is that he has no expertise regarding pain pumps. David Depo. at 57, 63-64, 78, 84 & 127. Even now that he works as a general litigation expert regarding medical devices, Dr. David still has not worked with pain pumps:

Q. ... But as far as pain pumps are concerned, have you ever given any opinions relative to the labeling, instructions for use or warnings outside the context of this litigation?

A. No.

Id. at 52. In fact, Dr. David admitted that *Rodriguez* is the only case for which he had ever reviewed material regarding pain pumps. *Id.* at 25-27.

Stryker does not dispute that Dr. David had general responsibility over the *acquisition* of medical devices at the hospitals where he worked—including pain pumps. *See* David Depo. at 44-46 & 53-57. But Dr. David described that role as a supervisory position that merely ensures that the technical experts follow the correct procedures:

I was the chairman [of the Medical Device Evaluation Committee]. There were 15 other expert members of the committee. My role would be to see that the process of evaluation throughout all this interdisciplinary participation follows a script that allows for the proper conclusion to be arrived at, that all the information is there, that engineering, biomedical engineering, is doing their bench testing, the clinicians are doing their clinical evaluations, the nurses are doing their nursing stuff.

Id. at 62 (emphasis added). That “general engineering experience” does not give Dr. David expertise over every medical device that his hospitals acquired. *See* *Pride*, 54 F. Supp. 2d at 761

(“Dr. Sissom’s general engineering expertise is clearly not particular to the science involved in this case”).

Instead, Rule 702 demands that Dr. David have “knowledge, skill, experience, training, or education” that “will assist the trier of fact.” FED. R. EVID. 702. This means, in particular, that the “[t]estimony of engineers may be excluded if it is not particular to the science involved in the case.” *Pride*, 54 F. Supp. 2d at 761. There is no debate that, outside of his general role in the acquisition of medical devices, Dr. David has never evaluated a pain pump for any reason. David Depo. at 57, 63-64, 78, 84 & 127.

B. Dr. David Is Not a Warnings Expert.

Nor is Dr. David qualified to give opinions about warnings and, in particular, whether warnings satisfy federal regulations. In short, Dr. David is an engineer (apparently an electrical engineer). David Depo. at 116-17. That does not automatically give him expertise about what constitutes adequate warnings:

Frequently, as was done here, plaintiffs’ counsel use their technical expert as their warnings expert even though it may be debatable that training, for example, as a mechanical engineer makes one also an expert on what warning or instructions should contain or where they should be placed.

Rhodes v. Cincinnati, Inc., 785 F.2d 310 (Table), 1986 WL 16402, *5 (6th Cir. Jan. 28, 1986) (copy attached as **Exhibit F**).

Dr. David has never written warnings for FDA-approved devices. David Depo. at 52. He has never been responsible for investigating or enforcing compliance with FDA warnings regulations. *Id.* at 51. Only the FDA enforces compliance with FDA regulations, and Dr. David is not an FDA employee. *Id.*

Indeed, medical warnings are designed to be read by doctors. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 430 (Tenn. 1994). Of course, Dr. David is not a doctor. David Depo. at

64 & 66. He does not teach medical students. *Id.* at 115-16. He has no expertise in orthopedics. *Id.* at 64. He has never even seen a pain pump in use following an orthopedic surgery. *Id.* He has never sat in on any training for a doctor's use of pain pumps. *Id.* at 65. Dr. David cannot comment one way or another on physicians' medical treatment decisions and what physicians should or should not do in general. *Id.* at 66-67. Thus, he is simply not qualified to evaluate warnings to doctors and to orthopedic surgeons in particular.

Dr. David points to only one basis for establishing some familiarity with medical warnings. In short, he has reviewed proposed labeling as part of an FDA advisory committee. *See id.* at 50 & 64. However, as Dr. David puts it himself, on that committee, Dr. David is "just an advisor." *Id.* at 51; *see also id.* at 122 ("Q. Now, in terms of the FDA advisory committees, would you agree that the advisory committees are just that, they are advisory only? A. Yes."). This committee does not make any final decisions about warnings. *Id.* Moreover, there are no uniform technical qualifications necessary to serve on these committees. For example, some of the members are consumers and patient advocates. *Id.* at 123. Aside from sitting on this advisory committee, Dr. David has never been responsible for reviewing or approving labeling of a device. *Id.* at 50-51.

C. Dr. David Is Not an FDA Expert.

Nor is Dr. David qualified as an FDA expert—despite the fact that the bulk of his report purports to attack Stryker's alleged compliance with FDA warnings regulations. In particular, Dr. David has never been an employee of the FDA or any of its various offices, including the Center for Devices and Radiological Health, the Office of Management Operations, the Office of Device Evaluation, the Office of Compliance, the Office of Science and Engineering, or the Office of Surveillance. David Depo. at 51-52.

As mentioned above, Dr. David emphasizes his contract work on an advisory committee to the FDA. But that hardly qualifies him as a regulatory expert—particularly not as a warnings regulatory expert. *See Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 975 (M.D. Tenn. 2002), *aff'd*, 89 Fed. Appx. 927 (6th Cir. Dec. 18, 2003) (“Nevertheless, an individual is not an expert in the abstract; expertise can only be judged within the context of a given case.”).

III. Dr. David's Opinions Are Unreliable because He Failed to Conduct any Research about the Magnitude of the Alleged Risk.

There is another blatant defect with Dr. David's opinions in this case. Dr. David did absolutely no research regarding the magnitude of the risk that Stryker should have allegedly warned about:

Q. Did you do any review of the medical literature -- and by medical literature I am talking about studies that discuss whether or not use of pain pumps in orthopedic procedures can lead to cartilage damage. Did you look at any of that body of medical literature for the purposes of your opinion in this case?

A. No.

Q. ... you just haven't looked at any of that literature?

A. Correct.

David Depo. at 72; *see also id.* at 130-32.

It is hard to imagine how an expert can begin to opine as to the necessary contents of a warning without some idea as to the level of risk involved. In addition to not determining the magnitude of the alleged risk, Dr. David did not even bother to compare the labeling for Stryker's pain pump with those of other pain pump manufacturers. David Depo. at 53; *cf. TENN. CODE ANN. § 29-28-105(b)*. Because Dr. David formed his opinions about Stryker's warnings without any foundation for his criticisms, this Court should exclude his opinions.

IV. Dr. David's Opinions about What Stryker Should have Done Differently Are Unreliable because He Failed to Establish Stryker's Knowledge at the Relevant Time.

Finally, there is one last missing foundational element in Dr. David's opinions. The Plaintiff's treatment in this case occurred in November 2004. *See* David Depo. at 67. Nevertheless, Dr. David fails to establish Stryker's alleged knowledge of the risks of this use of pain pumps as of November 2004. David Depo. at 101-05; *see also* David Depo. at 111-14 (showing Dr. David's inability to identify any case reports identifying the risks at issue before November 2004).

Instead of focusing on the date that Stryker learned of the alleged risk, Dr. David instead opines about Stryker's "knowledge" that tests had not yet been conducted. *Id.* at 102. Literally, Dr. David attacks Stryker for "knowing" that the risk was unknown—or that Stryker allegedly had "no knowledge of the risk" in his words. *Id.* at 101-02.

This approach is unreasonable. To determine the liability of a product manufacturer under Tennessee law, the Court should consider the manufacturer's knowledge of the risk:

In making this determination [whether a product was in a defective condition or unreasonably dangerous], the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury, is applicable.

TENN. CODE ANN. § 29-28-105(b). This Court should reject Dr. David's unusual efforts to blame Stryker for what it did *not* know at the relevant time.

Significantly, the lack of foundation is not limited to Stryker's knowledge. Dr. David admits that he does not know what the FDA's knowledge of the alleged risk was as of November 2004. *See* David Depo. at 97-98. Nor does he know the general knowledge in the industry at that time. *See id.* at 132. Therefore, there is no alternative basis by which to judge

“the state of scientific and technological knowledge available to the manufacturer.” *See* TENN. CODE ANN. § 29-28-105(b).

CONCLUSION

In light of the above, Stryker respectfully requests that the Court exclude the testimony of Dr. Yadin David in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of November, 2010, I electronically transmitted the foregoing document to the Clerk of the court using the ECF system for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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